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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/676,135 | 09/29/2000 | Bryan J. Boyle | 21272-034 | 9596 |

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| EXAMINER |
|---|
| SOUAYA, JEHANNE E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | 7 |

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/676,135 | Boyle et al. |
| **Examiner** | **Art Unit** |
| Jehanne Souaya | 1634 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Sep 29, 2000* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-30* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, and 14-16 drawn to polynucleotides, vectors and host cells comprising polynucleotides, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclasses 243 or 325, respectively.

II. Claims 10-13 and 25, drawn to polypeptides and to kits comprising these polypeptides, classified in class 530, subclasses 350 and 392.

III. Claim 17, drawn to antibodies, classified in class 424, subclass 130.1.

IV. Claims 18-20, drawn to methods of detecting polynucleotides, classified in class 435, subclass 6.

V. Claims 21-23, drawn to methods of detecting polypeptides or to methods of identifying compounds that bind polypeptides, classified in class 435, subclass 7.1.

VI. Claim 24, drawn to a method of producing a polypeptide comprising culturing the host cell comprising a polynucleotide sequence encoding the polypeptide under conditions sufficient to express the polypeptide in the cell and isolating the polypeptide, classified in class 435, subclass 71.1.

VII. Claims 26-28, drawn to nucleic acid arrays, classified in class 435, subclass 6.

VIII. Claims 29-30, drawn to methods of treating an individual in need of enhanced or inhibited activity of metallocarboxypeptidase-like polypeptide, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, and III are patentably distinct from each other because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, II, and III are patentably distinct from each other.

The inventions of groups I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to express proteins which is not required for the method of group IV.

The invention of group I is not related to the inventions of groups V and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of group I is not used in the methods of groups V and VIII. Further, these inventions have different modes of operation, different functions and different effects.

The inventions of group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used to make probes and primers for detection and amplification purposes.

The inventions of groups I and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as

claimed because 1) the utility of a polynucleotide array does not necessarily depend on the utility of each separate polynucleotide in the array, and 2) the polynucleotide array of Group VII can be used in a method to identify differential expression of many different genes. The subcombination has separate utility such as the distinct polynucleotides of Group I can be used in recombinant methods to express proteins.

The invention of group II is unrelated to the inventions of groups IV and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not used in the method of detecting a polynucleotide of group IV or the polynucleotide array of group VII.

The inventions of groups II and V & VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group II can be used to make fusion proteins with enzymatic functions which are not required for the method of detection of group V or the methods of treatment of group VIII.

The inventions of groups II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of group II can be made synthetically and does not have to be made using the process of group VI.

The invention of group III is unrelated to the inventions of groups IV, VI, VII and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group II are not used in the method of detecting a polynucleotide of group IV, the method of producing a polypeptide of group VI, the polynucleotide array of group VII, or the method of treating of group VIII. Further, these inventions have different modes of operation, different functions, and different effects.

The inventions of groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group III can be used in immunoassays which are not required for the method of detection of group V (the compound that binds to the polypeptide can be a specific ligand for the polypeptide).

The inventions of groups IV, V, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the method of detecting polynucleotides of group IV, the method of detecting polypeptides of group V, and the methods of treatment of group VIII have different modes of operation, different functions, and different effects. Each method requires different reagents, reaction conditions, and reaction parameters. Further, the inventions of groups IV, V, and VIII are unobvious over one another.

The inventions of groups IV and VI are patentably distinct from each other. The method of detecting polynucleotides of group IV requires different reagents, reaction parameters, and reaction conditions than the method of producing the polypeptide of group VI. Further, the method of detection of group IV does not require the method of producing the polypeptide of group VI and these methods are unobvious over one another.

The inventions of groups IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of detecting a polynucleotide of group IV can be carried out without the polynucleotide array of group VII, for example a ligand that binds specifically to the polynucleotide can be used in the method of group IV. Furthermore, the polynucleotide array of group VII can be used to identify the differential expression of many different genes.

The inventions of groups V and VI are patentably distinct from each other. The method of detecting polypeptides of group V requires different reagents, reaction parameters, and reaction conditions than the method of producing the polypeptide of group VI. Further, the method of detection of group V does not require the method of producing the polypeptide of group VI and these methods are unobvious over one another.

The inventions of groups V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting the polypeptide does not require the polynucleotide array of group VII, these inventions are not capable of use together and have different modes of operation, different functions, and different effects.

The inventions of groups VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of producing the polypeptide of group VI has different modes of operation, different functions, different effects and is not required for the polynucleotide array of group VII.

The invention of group VI is patentably distinct from the invention group VIII as the method of treating of group VIII do not require the method of producing the polypeptide of group

VI, the polypeptide can be produced synthetically. Furthermore, the reagents, reaction parameters, and reaction conditions to practice each invention are different.

The inventions of groups VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treating comprising administering an agonist or antagonist have different modes of operation, different effects and requires different reagents from the polynucleotide array of group VII, and further, these inventions are not capable of use together.

3. Upon election of a group above, applicant is further required to elect a single, patentably distinct nucleic acid or polypeptide sequence. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences or polypeptide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. Please note, since the polypeptides of SEQ ID NOS 6-16 are fragments of SEQ ID NO 4, they will be examined together if SEQ ID NO 4 is elected, however it is unclear how the sequences of SEQ ID NOS 17-19 are related to one another or to SEQ ID NO 4.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for the remaining groups, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Applicant note: the notice to change the attorney docket number has been received, and the appropriate corrections have been made.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Due to recent problems and delays regarding the receipt of mail at the USPTO, applicant is advised to submit a response to the above restriction requirement via facsimile, if possible.

The fax phone number for this Group is (703) 305-3014.

Jehanne Souaya
Patent examiner
Art Unit 1634

Jehanne Souaya
Feb. 8, 2002